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PATENT

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1/15/98  
Date

Paul Wardwell  
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

VAN NEST et al.

Serial No.: 08/418,870

Art Unit: 1813

Filing Date: April 7, 1995

Examiner: H. Auer

Title: ADJUVANT FORMULATION COMPRISING  
SUBMICRON OIL DROPLET EMULSION

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. Copies of the information and completed PTO-1449 forms are submitted herewith. The Examiner is respectfully requested to make this information of official record in the application. A check to cover the \$240 fee is attached. The information includes:

Copy of Decision Revoking the European Patent;

Documents cited in the Decision Revoking the European Patent:

U.S. Patent No. 3,790,665, issued February 5, 1974 to Glass et al.;

European Patent Publication No. A-0 135 376, published March 27,  
1985;

01/26/1998 SDAVIS 00000154 08418870 240.00 OP  
02 FC:126

European Patent Publication No. A-0 382 271, published August 16, 1990;

Affidavit of John D. Barackman and Mastersizer Results;  
Becher, *Emulsions Theory and Practice*, 2nd Edition, Chapter 5, (1965);

Herbert, "The Mode of Action of Mineral-Oil Emulsion Adjuvants on Antibody Production in Mice," *Immunology* 14:301-318 (1968);

Kaufman et al., "Spectral Absorption Measurements for Determination of Ease of Formation and Stability of Oil in Water Emulsions," *J. Dispersion Science and Technology* 2(4):475-490 (1981);

Ott et al., *Vaccine Design: The Subunit and Adjuvant Approach*, Chapter 10, Powell et al., Ed., Plenum Press, New York;

Sanchez-Pescador et al., "The Effect of Adjuvants on the Efficacy of a Recombinant Herpes Simplex Virus Glycoprotein Vaccine," *J. Immunology* 141:1720-1727 (1988);

Silvestri et al., "Theoretical Evaluation of Dispersed Droplet Radii in Submicron Oil-in-Water Emulsions," *International Journal of Pharmaceutics* 50(2):141-146 (1989);

Singh et al., "Parenteral Emulsions as Drug Carrier Systems," *J. Parenteral Science & Technology* 40(1):34-41 (1986);

Woodard et al., "Stable Oil-in-Water Emulsions: Preparation and Use as Vaccine Vehicles for Lipophilic Adjuvants," *Vaccine* 3:137-144 (1985); and

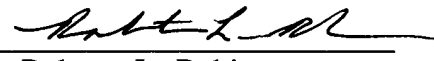
Yarkoni et al., "Influence of Type of Oil and Surfactant Concentration on the Efficacy of Emulsified *Mycobacterium bovis* BCG Cell Walls to Induce Tumor Regression in Guinea Pigs," *Infection and Immunity* 28(3):881-886 (1980);

Statement of Grounds of Appeal to the Decision Revoking the European Patent.

This Supplemental Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 1/15/98

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